

Authority (collectively “Plaintiffs”),² are third party payors who seek to recover under the federal RICO statute and state law, expenses they have incurred, and continue to incur, due to alleged “off-label” marketing and sales of Risperdal. The Court previously dismissed Plaintiffs’ consolidated amended class action complaint filed in 2008 and provided Plaintiffs an opportunity to amend their complaint consistent with the Court’s Opinion dated December 23, 2008.³ In this new Complaint, Plaintiffs re-allege that Defendants engaged in a fraudulent scheme to promote the off-label use of Risperdal, thereby violating: (1) 18 U.S.C. § 1962(c), Conducting the Affairs of the Enterprise Through a Pattern of Racketeering Activity (“RICO”); (2) 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c); and (3) N.J.S.A. 2C:41-1, New Jersey’s RICO statute (“NJ RICO”). In addition, Plaintiffs assert various new causes of action pursuant to state law. In the instant matter, Defendants move to dismiss the Complaint arguing that the RICO related claims, Counts I-III, are substantively flawed and have not met the strictures of the Court’s Opinion, and that the remaining state law claims, Counts IV-X, fail for a lack of causation and/or reliance. This second time around, Plaintiffs’ new Complaint fares no better than its predecessor, and therefore, for the reasons that follow, the Court grants Defendants’ motion to dismiss.

² In this class action lawsuit, four separate complaints were filed, and then consolidated into this action. District 1199P Health and Welfare Plan is a jointly trustee employee benefit trust fund and an employee welfare benefit plan located in Pennsylvania. (Compl. ¶ 10). Ironworkers Local Union No. 399 and Participating Employers Health and Welfare Funds is a health and welfare fund located in Westville, New Jersey. *Id.* at ¶ 11. International Brotherhood of Electrical Workers Local 98 is an employee welfare benefit plan and employee benefit plan located in Philadelphia, Pennsylvania. *Id.* at ¶ 12. Southeastern Pennsylvania Transportation Authority employs a workforce of approximately 9,000 people and provides medical benefits for eligible employees; its principle place of business is in Philadelphia, Pennsylvania. *Id.* at ¶13.

³ The parties agreed to dismiss the previous case, Civil Action No. 06-3044, and Plaintiffs filed the Complaint in the present case under a new civil action number.

I. Background and Procedural History

Since Defendants have moved to dismiss Plaintiff's claims pursuant to Fed. R. Civ. P. 12(b)(6), the following relevant facts assume the allegations in the Complaint to be true. Plaintiffs initially filed a complaint in 2008 ("2008 Complaint"), which was dismissed without prejudice by this Court. See Dist. 1199P Health & Plan v. Janssen, L.P., No. 06-3044, 2008 U.S. Dist. LEXIS 103526 (D.N.J. Dec. 23, 2008) (hereinafter "District 1199P I"). The 2008 Complaint alleged that Defendants violated: (1) the RICO Act; (2) RICO conspiracy; and (3) the New Jersey RICO Act. Among other deficiencies, this Court explained that the 2008 Complaint failed to sufficiently allege a cognizable RICO injury under federal or New Jersey law. The Complaint in the instant matter attempts to cure the defects of the 2008 Complaint, and asserts new claims under state law.⁴ In deciding the present motion, this Court will refer to its previous Opinion.

The Complaint alleges that Defendants illegally promoted Risperdal for off-label purposes through a comprehensive and carefully orchestrated scheme. (See Compl. ¶ 2). The Complaint avers in detail that the scheme involved a fraudulent and deceptive marketing program that led Plaintiffs and other third party payors ("TPPs") to suffer direct economic harm. Id. at ¶¶ 2, 5. Specifically, Plaintiffs alleged that they were paying approximately 80% of the purchase price of Risperdal -- a drug nearly ten times as expensive as other, more effective, safer and more tolerable drugs -- for their insureds. Id.

⁴ Plaintiffs' new 112-page Complaint is comprised of 390 paragraphs of allegations regarding Defendants' alleged scheme to promote Risperdal. In those paragraphs, Plaintiffs point to Defendants' promotional campaigns, publication strategies and other marketing techniques, along with numerous scientific studies related to Risperdal, in an effort to show that Defendants engaged in an illegal scheme with others to defraud Plaintiffs. However, distilled to their essence, the allegations of this Complaint, like those in the original complaint, do not meet the pleading requirements under the law.

Risperdal is currently sold and marketed by Defendants, see Id. at ¶¶ 14, 15, to patients suffering from schizophrenia, bipolar mania, and autistic disorder under strict regulation by the Food and Drug Administration (“FDA”). See Id. at 31–33. For off-label purposes,⁵ Risperdal has been prescribed to adults for dementia, Alzheimer’s disease, some forms of depression, Obsessive-Compulsive Disorder, Post-Traumatic Stress Disorder, Personality Disorders, anxiety, sleep disorders, anger management, mood enhancement or mood stabilization, and behavioral disorders not caused by adult schizophrenia or bipolar I disorder. Id. at ¶ 47. The drug has also been prescribed off-label to treat children and adolescents for general mood and behavior disorders. Id. In 2006, Risperdal was used off-label 66 percent of the time. Id. at ¶ 48.

Plaintiffs assert that Risperdal, as well as other second-generation antipsychotics (“SGAs”) are neither more effective nor safer than older, cheaper antipsychotics.⁶ Id. at ¶ 50. However, to make Risperdal marketable and profitable, Defendants aggressively marketed the drug by overstating the drug’s uses and understating or concealing the seriousness and frequency of Risperdal’s potentially life-threatening side effects.⁷ Id. at ¶ 51. Plaintiffs further allege that Defendants’ aggressive and fraudulent marketing was due to Defendants’ understanding that schizophrenia represented only 35 percent of antipsychotic prescriptions, and therefore, “[a]ggressive expansion of Risperdal use in

⁵ The FDA regulates off-label use of drugs, which “refers to the use of a prescription drug for any purposes -- any indication, dosage form, dosage regimen, or population - not specifically approved by the FDA.” In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 06-5774, 2009 U.S. Dist. LEXIS 58900, at *2 (D.N.J. July 10, 2009) (“In re Schering-Plough I”) (citing Washington Legal Found. V. Henney, 202 F.3d 331, 332 (D.C. Cir. 2000)).

⁶ This Court notes that Plaintiffs point to *inconclusive studies*, or a lack of studies, for certain off-label uses of Risperdal to support their assertions that Risperdal is inferior or no more effective than older, cheaper antipsychotics. See Id. at ¶¶ 50, 72, 92, 98, 174, 190.

⁷ For example, Plaintiffs allege that on November 10, 2003, Defendants sent a “Dear Health Care Provider” letter that misrepresented Risperdal’s risks, including the statement that: “Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL.” Id. at ¶ 162.

other indications [was] therefore mandatory.” *Id.* at ¶ 54 (citing a 2010 *Bloomberg* article). As part of this aggressive expansion, Defendants conducted meetings and adopted strategies to expand Risperdal for off-label uses. *Id.* at ¶¶ 56-57. Indeed, Plaintiffs cite to a J & J internal report, which indicated that names were provided to the company in an effort to increase the call frequency on resistant prescribers in order to influence them to use more Risperdal for off-label purposes; in particular, for elderly patients with dementia,⁸ Psychosis in Alzheimer’s Disease (“PAD”), autism (prior to its FDA approval in 2006), ADHD, disruptive behavior and agitation in children, mood and anxiety disorders, bipolar disorders in children and adolescents, post-traumatic stress disorder (“PTSD”), and refractory depression. *Id.* at ¶¶ 70, 82, 89-94, 101. Because Defendants allegedly withheld or provided false information regarding the true effects and safety of Risperdal, prescribing physicians did not have the necessary information to make informed decisions about prescribing Risperdal for off-label purposes. *Id.* at ¶ 106. Ultimately, according to Plaintiffs, Defendants knew that Plaintiffs and other TPPs would bear the responsibility of paying for Risperdal prescriptions, rather than other more efficacious, safe, and less expensive medications (or no medicine at all). *Id.* at ¶ 116. Plaintiffs claim that the injury they suffered -- the excess money Plaintiffs paid Defendants for the Risperdal that they would not have purchased “but for” Defendants’

⁸ For example, in a 2000 memorandum, a J & J employee stated that the Risperdal initiative “has generated an all time market share high of 55.5% throughout the 1st quarter of 2000. This market share represents Omnicare’s ability to persuade physicians to write Risperdal in the areas of Behavioral Disturbances associated with dementia.” (Compl. ¶ 72). Omnicare is the nation’s largest provider of pharmaceuticals to nursing homes. *Id.* at ¶ 4. This Court notes that Plaintiffs do not explain Omnicare’s contacts with physicians; indeed, the Complaint states in a previous paragraph that Omnicare and Defendants made an agreement whereby Omnicare would provide physicians names for *Defendants* to contact and persuade to prescribe Risperdal. *See Id.* ¶¶ 70-72. Furthermore, Plaintiffs do not provide any allegations that Defendants were persuading physicians to prescribe Risperdal for off-label purposes with regard to conditions such as Psychosis in Alzheimer’s Disease (“PAD”), autism (prior to its FDA approval in 2006), ADHD, disruptive behavior, agitation in children, mood and anxiety disorders, bipolar disorders in children and adolescents, post-traumatic stress disorder (“PTSD”), and refractory depression. *See Id.* at ¶¶ 82-89.

fraud -- is unaffected by whether any patient who took Risperdal became ill or suffered any harm as a result of ingesting the drug. Id. at ¶ 117.

To support their assertion that Risperdal is harmful for its off-label uses, Plaintiffs aver that in 2003, a researcher at the FDA identified 131 cases of risperdone-associated diabetes or hyperglycemia in an FDA reporting database. Id. at ¶ 160. Of the 131 cases, 78 were newly diagnosed hyperglycemia, 46 were exacerbations of a preexisting disease, and 7 were unclassifiable.⁹ Id. Plaintiffs argue that Defendants knew, or should have known, that the risk of new-onset diabetes mellitus or hyperglycemia associated with Risperdal is significantly higher than with older, cheaper, and equally effective “typical” antipsychotic drugs. Id. at ¶ 169.

Plaintiffs also allege that Defendants “caused” Plaintiffs and other TPPs to list Risperdal on their formularies -- a list of approved drugs for which payment will be made -- as part of their scheme to make Plaintiffs pay for expensive Risperdal prescriptions.¹⁰ Id. at ¶ 104. Formularies are prepared by Pharmacy Benefit Managers (“PBMs”), who act as agents for TPPs, see Id. at ¶ 108, and Plaintiffs rely almost exclusively on their PBMs to make formulary decisions. Plaintiffs claim that if they had been aware that Defendants were illegally promoting Risperdal for off-label uses that were unsafe and/or ineffective for their beneficiaries, they would have requested that Risperdal either be placed on a

⁹ Plaintiff’s Complaint states that “[d]espite having knowledge of Risperdal’s association with hyperglycemia and diabetes mellitus, and despite the request by the FDA [in September 2003], Defendants fought the label change and refused to take action to correct the defect with the Risperdal product labeling for several months.” (Compl. ¶ 160). However, Plaintiffs do not indicate whether the patients in the 2003 study took the medication before the label change, or whether these patients were prescribed Risperdal for off-label use. In addition, Plaintiffs do not allege that these 131 individuals in the study were their insureds or employees. More importantly, Plaintiffs do not indicate whether the individuals were taking Risperdal for on- or off-label uses.

¹⁰ Plaintiffs allege that average monthly costs for Risperdal range from \$382 to \$1434. (Compl. ¶ 104).

restricted formulary that would require prior authorization, or be removed from the formulary entirely.¹¹ See Id. at ¶¶ 114, 115, 285.

Regarding Defendants' marketing tactics, Plaintiffs allege that Defendants employed the services of a network of third-party marketing firms to effectuate their scheme to market Risperdal for off-label uses. Id. at ¶ 204. Indeed, Defendants allegedly controlled the marketing firms' activities, which consisted of physicians disseminating information about off-label uses of Risperdal in Continuing Medical Events ("CME"), consultants' meetings, speaking engagements and other programs. Id. In addition, Plaintiffs allege that Defendants employed publication strategies to generate favorable articles promoting the off-label uses of Risperdal.¹² Id. at ¶¶ 205, 230, 247. Plaintiffs claim that to lure doctors to participate in such marketing strategies, Defendants offered substantial funding to doctors willing to speak favorably about Risperdal.¹³ Id. Plaintiffs also claim that the key strategy to promote Risperdal was through "thought leaders," who were doctors that would promote Risperdal through peer-selling programs. Id. at ¶ 212.

¹¹ Plaintiffs do not allege that any PBM directly relied on Defendants' information in making the decision to include Risperdal on any formulary, including Plaintiffs' formulary. (Compl. ¶ 113–15.). Plaintiffs simply state that had they known about Defendants' illegal promotion of Risperdal for off-label purposes, they would have "taken action against utilization anomalies where Risperdal was predominately being prescribed for unsafe and ineffective off-label uses." Id. at ¶ 115. Plaintiffs also do not allege that the PBMs would not have recommended Risperdal for the formulary "but for" Defendants' illegal promotion of the drug. See Id.

¹² See District 1199P I ("For example, Plaintiffs allege 'Dr. Charles Nemeroff, the presenter for the 2007 CME presentation entitled *Add On Atypical Antipsychotics Efficacious in Short Term for Unipolar Depression*, references the ARISE-RD study, which was an attempt to demonstrate the efficacy of Risperdal for depression. . . . Dr. Nemeroff claimed that a peer-reviewed study showed Risperdal improves sexual functioning, when the effects of treatment on sexual functioning were not mentioned in the ARISE-RD study. Additionally, Dr. Nemeroff claimed that the study showed Risperdal demonstrates efficacy over placebo, which the ARISE-RD study in fact did not. . . . Dr. Nemeroff has been a long time key opinion leader for Defendants and has participated in a Janssen-financed journal supplement in 2005.'").

¹³ Plaintiffs do not specify whether these doctors spoke favorably about Risperdal for approved FDA uses, off-label uses, or both. In addition, the Complaint does not allege whether these doctors were persuaded by Defendants' "funding" to speak favorably about Risperdal.

During these programs, the “thought leaders” would provide allegedly false information regarding Risperdal’s safety, efficacy, and widespread use and popularity. *Id.* Plaintiffs assert that the planning and coordination of the CMEs by the marketing firms required extensive use of the wires and mails, including the mailing of invitations to physicians, the mailing of proposals to the accrediting institutions, booking of hotels and airplane tickets, the arrangement of meals, the scheduling of telephone conference calls, the development and modification of tactical plans, and the coordination of Risperdal presentation content for the events.¹⁴ *Id.* at ¶ 215. Plaintiffs allege that “Defendants’ marketing activities *naturally* led to increases in sales for Risperdal as a result of the marketing’s influence on physician behavior.”¹⁵ *Id.* at ¶ 225 (emphasis added).

Plaintiffs also aver that these physicians received direct payments in order to promote Defendants’ alleged fraudulent scheme. Indeed, Plaintiffs state that these financial incentives include expensive dinners and lavish vacations in return for

¹⁴ Plaintiffs also generally state that the mails and wires were used to perpetuate Defendants’ fraud through thousands of communications, including marketing and advertising materials about the off-label uses of Risperdal, discussions related to payments to physicians for articles misrepresenting off-label uses of Risperdal, communications with the Marketing Firm Enterprise and physician participants that fraudulently misrepresented the safety and efficacy of Risperdal, and communications to TPPs, PBMs, physicians and patients in order to induce purchases of Risperdal based on misrepresentations. (Compl. ¶ 287).

¹⁵ For example, Plaintiffs allege that Defendants targeted a health assistance program called TeenScreen. Quoting a *Washington Post* Article, the Complaint states: “‘The growing use of screening has coincided with a rapid increase in the number of youngsters being prescribed powerful antipsychotic medications such as Risperdal and Zyprexa that have not been specifically approved for use by children.’” (Compl. ¶ 239). Plaintiffs state that TeenScreen has a “connection” or “affiliation” with Defendants and other pharmaceutical companies. *Id.* Plaintiffs claim that students responded to a TeenScreen survey in May 2002, which was conducted by the National Alliance on Mental Illness, an organization that receives direct funding from pharmaceutical companies like Defendants. *Id.* Plaintiffs do not indicate how Defendants used the information from the surveys. *Id.* Similarly, Plaintiffs describe a *New York Times* article, which quoted a J&J sales representative who worked for the company until 2002. She stated: “[T]he vast majority of the time that we did any sort of paid relationship with a physician, they increased the use of our drug . . .” *Id.* at ¶ 254. However, Risperdal was not specifically mentioned, and Plaintiffs do not provide any examples of physicians who claim to have been influenced by Defendants to prescribe Risperdal.

prescribing Risperdal, and excessive payments to physicians for conducting clinical trials of Risperdal. *Id.* at ¶ 244. In Massachusetts, Plaintiffs specifically note that four patients' medications were changed to Risperdal for non-medical reasons and without their consent. *Id.* Plaintiffs submit that the physicians wanted to be eligible for a drug trial sponsored by Janssen, wherein each physician would have been paid upon completion of the trial.¹⁶ *Id.* at ¶ 259.

In sum, Plaintiffs claim that as a result of Defendants' fraudulent scheme, "the medical literature and usage practices relating to Risperdal have been severely contaminated by years of false and misleading information regarding the scientific, medical and clinical data relating to the safety, medical efficacy, effectiveness and usefulness of Risperdal for off-label conditions." *Id.* at ¶ 289. In turn, because "studies have illustrated that physicians can prescribe lower-cost and equally effective alternatives to Risperdal for both FDA-approved conditions and conditions for which Defendants have promoted the off-label use of Risperdal," Defendants' wrongful marketing, advertising and promotion of Risperdal caused Plaintiffs to pay Defendants for Risperdal that they would not have otherwise purchased. *Id.* at ¶ 116–19, 265.

II. Standard of Review

The Federal Rules of Civil Procedure provide that a complaint "shall contain (1) a short and plain statement of the grounds upon which the court's jurisdiction depends ...

¹⁶ This Court notes that the *Boston Globe* article cited by Plaintiffs indicates that physicians, in order to conduct the study, needed approval from the review boards at Boston University and the Department of Mental Health. Indeed, the physician who changed his patients' medications made the unilateral decision to change the medications before approval from the review boards. There is no indication that Janssen or any other defendant suggested that the physician change his/her patients' medications. In fact, the physician would have received funding from defendant Janssen if he/she had waited for approval from the review boards. In addition, the article notes that Risperdal was being used *not* for off-label purposes, but rather, for adult patients with schizophrenia. See Ellen Barry, *Drugs of 4 patients subbed without OK*, The Boston Globe, November 10, 2003, http://www.boston.com/news/local/articles/2003/11/10/drugs_of_4_patients_subbed_without_ok/.

(2) a short and plain statement of the claim showing that the pleader is entitled to relief, and (3) a demand for judgment for the relief the pleader seeks.” Fed.R.Civ.P. 8(a). The purpose of a complaint is “to inform the opposing party and the court of the nature of the claims and defenses being asserted by the pleader and, in the case of an affirmative pleading, the relief being demanded.” 5 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1182 (3d ed. 2004).

In reviewing a motion to dismiss for failure to state a claim under 12(b)(6), a Court must take all allegations in the complaint as true, viewed in the light most favorable to the plaintiff “and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), the Supreme Court “retired” the language in Conley v. Gibson, 355 U.S. 41, 45-46 (1957), that “a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” Twombly, 550 U.S. at 561 (quoting Conley, 355 U.S. at 45-46). Rather, the factual allegations in a complaint “must be enough to raise a right to relief above the speculative level.” Id. at 555. The Third Circuit summarized the pleading requirement post-Twombly:

The Supreme Court's Twombly formulation of the pleading standard can be summed up thus: ‘stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest’ the required element. This ‘does not impose a probability requirement at the pleading stage,’ but instead ‘simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of ‘the necessary element.’

Phillips, 515 F.3d at 234 (quoting Twombly, 550 U.S. at 556).

In affirming that the Twombly standard applies to all motions to dismiss, the Supreme Court recently further clarified the 12(b)(6) standard. “First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009). “Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.” Iqbal, 129 S.Ct. at 1950. Accordingly, “a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth.” Id. In short, “a complaint must do more than allege the plaintiff’s entitlement to relief. A complaint has to ‘show’ such an entitlement with its facts.” Fowler v. UPMC Shadyside, 578 F.3d 203, 211 (3d Cir. 2009).

The Third Circuit recently reiterated that “judging the sufficiency of a pleading is a context-dependent exercise” and “[s]ome claims require more factual explication than others to state a plausible claim for relief.” West Penn Allegheny Health System, Inc. v. UPMC, 627 F.3d 85, 98 (3d Cir. 2010). This means that, “[f]or example, it generally takes fewer factual allegations to state a claim for simple battery than to state a claim for antitrust conspiracy.” Id. That said, the Rule 8 pleading standard is to be applied “with the same level of rigor in all civil actions.” Id. (quoting Iqbal, 129 S.Ct. at 1953).

III. Discussion

A. Counts I and III: RICO and NJRICO¹⁷

Plaintiffs argue that Defendants’ alleged conduct violated the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(c), which “makes it

¹⁷ The analysis which pertains to federal RICO applies with equal force to NJRICO because the New Jersey Supreme Court has expressed that “the New Jersey RICO statute was and should be consistent with the federal RICO statute.” Ross v. Celtron Int’l, Inc., 494 F. Supp. 2d 288, 302 n.4 (D.N.J. 2007) (citing Cetel v. Kirwan Fin. Group, Inc., 460 F.3d 494, 510 (3d Cir. 2006)).

unlawful ‘for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity.’” In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 362 (3d Cir. 2010) (citing 18 U.S.C. § 1962(c)). For Plaintiffs to plead a civil RICO claim under 18 U.S.C. § 1962(c), they must allege (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity. Sedima v. Imrex Co., 473 U.S. 479, 482-83 (1985). The term “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” Ins. Brokerage, 618 F.3d at 362–63 (citing 18 U.S.C. § 1961(4)). With respect to the pattern of racketeering activity, the statute “requires at least two acts of racketeering activity within a ten-year period” which “may include, inter alia, federal mail fraud under 18 U.S.C. § 1341 or federal wire fraud under 18 U.S.C. § 1343.” Id. (citing 18 U.S.C. § 1961(1)(5) and Lum v. Bank of Am., 361 F.3d 217, 223 (3d Cir. 2004)). In addition, the Third Circuit has articulated that Section 1964(c) requires “a RICO plaintiff to make two related but analytically distinct threshold showings . . . (1) that the plaintiff suffered an injury to business or property; and (2) that the plaintiff’s injury was proximately caused by the defendant’s violation of 18 U.S.C. § 1962.” Maio v. Aetna, Inc., 221 F.3d 472, 483 (3d Cir. 2000). In that regard, the Court will separately analyze the each element under RICO -- injury, causation, enterprise, and racketeering activity -- to assess whether Plaintiffs have met their burden.

1. Injury

Defendants submit that Plaintiffs can never establish standing under RICO because their alleged injury -- excessive payment for Risperdal prescriptions as TPPs -- is not cognizable under the statute. Defendants maintain that Plaintiffs have not suffered a “concrete financial loss” as required by the case law because Plaintiffs fail to allege that Risperdal caused any of their participants to suffer physical harm, and that Risperdal was ineffective for any participant. See Maio, 221 F.3d at 483 (quoting Steele v. Hospital Corp. of Am., 36 F.3d 69, 70 (9th Cir. 1994) (“[A] showing of injury requires proof of a concrete financial loss and not mere injury to a valuable intangible property interest.”)). To rebut, Plaintiffs argue that they have alleged injury by asserting that because Risperdal is ineffective, or has not been proven effective in treating off-label conditions, Plaintiffs paid too much for Risperdal when cheaper alternatives were available. (Compl. ¶¶ 50, 169). In addition, Plaintiffs claim that “but for” Defendants’ fraud, they would not have purchased Risperdal, or they would have taken action against utilization anomalies where Risperdal was predominately being prescribed for unsafe and/or ineffective off-label uses. Id. at ¶¶ 114, 115, 285.

In this connection, this Court made clear in District 1199P I that “Plaintiffs’ injury theory based on financial losses of overpayment that Plaintiffs purportedly sustained by paying for this ‘inferior’ drug is inadequate for sustaining a RICO injury, *absent allegations that Defendants’ drug was on some level ‘inferior and therefore ‘worth less’ than what [Plaintiffs] paid for it.*” District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *29 (emphasis added) (citing Maio, 221 F.3d at 486). This Court relied on the Third

Circuit's decision in Maio. In that case, the Third Circuit elaborated on the theory of injury proposed here by Plaintiffs:

Stated another way, in the context of this case, we hold that appellants cannot establish that they suffered a tangible economic harm compensable under RICO unless they allege that health care they received under Aetna's plan actually was compromised or diminished as a result of Aetna's management decisions challenged in the complaint. It seems clear to us that unless appellants claim that Aetna failed to provide sufficient health insurance coverage to the members of their HMO plan in the sense that such individuals were denied medically necessary benefits, received inadequate, inferior or delayed medical treatment, or even worse, suffered personal injuries as a result of Aetna's systemic policies and practices, there is no factual basis for appellants' conclusory allegation that they have been injured in their "property" because the health insurance they actually received was inferior and therefore "worth less" than what they paid for it. Of course, such losses would have to be alleged and proven on an individual basis. Inasmuch as we hold that appellants have not alleged facts sufficient to establish the fact of damage, i.e., appellants' injury to property stemming from their purchase of an 'inferior' product, they have no cause of action under RICO.

Maio, 221 F.3d at 488 (emphasis added). As recently as last year, Judge Chelser in this district dismissed a complaint by TTPs alleging substantially similar claims against another drug manufacturer by explaining that "the TPPs' asserted 'overpayment' for the Subject Drugs based on the existence of cheaper alternative medications or treatments that were available to a beneficiary's prescribing doctor does not make the product received inferior or worth less and therefore does not constitute RICO injury." In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 06-5774, 2010 U.S. Dist. LEXIS 56621, at *18 (D.N.J. Jun. 9, 2010).

While Plaintiffs attempt to cure the defects in their 2008 Complaint by peppering the Complaint with language that suggests alternative medications were "more effective" or "safer than Risperdal," these allegations are simply conclusory in nature and as the

Court noted supra, the Court need not accept as true unsupported conclusions and unwarranted inferences. Baraka v. McGreevey, 481 F.3d 187, 195 (3d Cir. 2007); see, e.g., Compl. ¶¶ 5, 115, 153, 180, 256. Indeed, nowhere in the Complaint do Plaintiffs allege sufficiently that Risperdal was an inferior drug over other drugs. Instead, Plaintiffs cite studies indicating that Risperdal had a greater association with adverse effects, such as new onset diabetes, prolactin side effects, hyperglycemia and weight gain. See, e.g., Compl. at ¶ 143 (the results of one study revealed that the incidence rate of new onset diabetes per 100,000 individuals was 2,724.34 for Risperdal, 1,961.94 for Olanzapine, 3,560.00 for Clozapine, 0.00 for Quetiapine, and 3.905.73 [sic] for Haloperidol); Id. at ¶ 154 (the results of a 2002 report revealed that Risperdal has proven less effective than Clozapine for psychotic symptoms, and Risperdal had a high incidence of prolactin side effects); Id. at ¶ 160 (the FDA found 131 cases of risperdone-associated diabetes or hyperglycemia in a reporting database); Id. at ¶ 194 (studies in children and adolescents showed risperidone treatment was associated with a 2- to 4-fold increase in mean measures in serum prolactin in children with autism). However, Plaintiffs fail to allege whether these studies were conducted to discover side effects for on- or off- label uses of Risperdal. This is significant because Plaintiffs' claim is entirely based on Defendants' alleged fraudulent marketing which induced patients to purchase Risperdal for off-label purposes.¹⁸ Indeed, it appears that the foregoing studies are consistent with Risperdal's

¹⁸ While Plaintiffs allege in their Complaint that "Defendants [] deliberately misrepresented the scientific medical and clinical data concerning the safety, efficacy, effectiveness, usefulness and superiority of Risperdal over comparable drugs for both on- and off-label uses," the Complaint does not allege any misrepresentations made by Defendants regarding on-label uses of the drug. (Compl. ¶ 3). Indeed, the 112 page Complaint is dedicated to Plaintiffs allegations regarding Defendants' fraudulent marketing of Risperdal for off-label purposes. See Id. at p. 15 ("Defendants' Deliberate Decision to Promote Risperdal's Off-Label . . .") (emphasis added); Id. at p. 33 ("Defendant's Dissemination of False and Misleading Scientific, Medical & Clinical Data Regarding the Safety, Efficacy and Effectiveness of Risperdal's Off-

on-label uses of Schizophrenia, irritability associated with autistic disorder in children and adolescents, and Schizophrenia and Mania associated with Bipolar I in children and adolescents. See Id. at ¶¶ 42-45.¹⁹

Plaintiffs additionally note a study that indicates Risperdal was more likely to cause hyperglycemia in patients with dementia than either a placebo or another drug, Haloperidol. These allegations do not suggest or necessarily imply that Risperdal is inferior because they simply point to greater incidences of a certain side-effect. Moreover, Risperdal and Haloperidol are in different drug classifications (atypical antipsychotic and typical antipsychotic, respectively, see Id. at ¶¶ 37, 41), and therefore produce different side effects on individual patients. See Id. at ¶ 39. This is supported by Plaintiffs' Complaint, which asserts that Haloperidol is associated with a greater number of new onset diabetes in patients than Risperdal. See Id. at ¶ 143. Thus, Plaintiffs essentially complain that they paid too much for a medicine that they have not sufficiently alleged to be inferior or worth less. See Maio, 221 F.3d at 488 (holding that generalized assertions of "overpayment" for "inadequate" health care did not constitute RICO injury).

Even more problematic, Plaintiffs do not identify any participant in their health plans who received an ineffective or unsafe off-label Risperdal prescription, or any participant who allegedly would have been treated with a less expensive and more

Label Uses") (emphasis added); Id. at p. 52 ("Defendants' Creation of the Marketing Firms Enterprise and Implementation of the Publication Strategy to Promote Risperdal for Off-Label Use") (emphasis added).

¹⁹ Further, Plaintiffs' suggestion that Clozapine is "more effective" for psychotic disorders does not imply Risperdal's inferiority, since Plaintiffs also allege that Clozapine is associated with toxicity, and has largely gone undistributed since the 1990s. (See Compl. ¶¶ 39-40). Similarly, the study regarding new onset diabetes indicates that Haloperidol and Clozapine have higher incidences of new onset diabetes than Risperdal. Therefore, Risperdal may in fact be "superior" to these drugs in connection with that side-effect.

effective medicine if that participant had not received Risperdal. In re Schering-Plough I, 2009 U.S. Dist. LEXIS 58900, at *14-15 (“Plaintiffs nowhere allege facts to support the theory that the named [plaintiffs] actually paid for one or more of the Subject Drugs to treat an off-label indication for which the drug was ineffective.”).²⁰ Here, “nowhere do Plaintiffs allege that any beneficiaries, insured, or employees taking Risperdal ‘received [an] inadequate [or] inferior [drug] or even worse, suffered personal injuries as a result of Defendants’ alleged misrepresentations,” and therefore, the studies to which Plaintiffs refer do not support Plaintiffs’ allegations of a cognizable RICO injury.”²¹ District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *30 (citing Maio, 221 F.3d at 488).

For legal support, Plaintiffs again rely on In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 531 (3d Cir. 2004), and Desiano v. Warner-Lambert Co., 326 F.3d 339, 349-50 (2d Cir. 2003), for the proposition that TPPs suffer direct economic harm when, as a result of the pharmaceutical companies’ alleged misrepresentations, they pay “supracompetitive” prices for the brand drug instead of purchasing a lower-priced generic drug. However, Plaintiffs’ reliance on these cases is misplaced. As this Court previously explained, no RICO claims were alleged in Warfarin or Desiano; rather, these cases involved claims arising out of federal anti-trust laws and consumer fraud. See District

²⁰ In re Schering-Plough I is factually and legally analogous to this case. While Plaintiffs disagree with the decision in In re Schering-Plough I, they neither provide any legal argument nor distinguish the facts of that case from this one in support of their disagreement. This Court, on the other hand, finds that In re Schering-Plough I is persuasive.

²¹ Plaintiffs even admit that their position is that their alleged injury “is unaffected by whether any given patient ingested Risperdal or suffered Adverse Events.” (Compl. ¶ 113).

1199P I, 2008 U.S. Dist. LEXIS 103526, at *21. As such, these cases are not helpful to determining whether there is a cognizable RICO injury.²²

Plaintiffs also attempt to assert a RICO injury by alleging that absent Defendants' fraud, Plaintiffs would have reconsidered Risperdal's placement on its formulary list, or otherwise taken action against utilization anomalies where Risperdal was predominately being prescribed for unsafe and ineffective off-label uses. (See Compl. ¶ 114, 115, 285; see also Memorandum of Law in Opposition to Defendants' Motion to Dismiss p. 15) ("Opposition Memo"). However, Plaintiffs' Complaint merely alleges that Defendants' products are not conclusively effective for off-label uses, rather than alleging that the product is unsafe or ineffective for off-label uses.²³ As stated in District 1199P I, "the [D]efendants' misrepresentation 'could in no way have reduced the value of the [product] that [P]laintiffs actually purchased,' but rather the [D]efendants 'simply could have induced [P]laintiffs to buy [the product over other products]. The Second Circuit

²² Plaintiffs also rely on In re Zyprexa Prods. Liab. Litig., 493 F. Supp. 2d 571, 576 (E.D.N.Y. 2007). However, this Court need not elaborate on Plaintiffs' position here because the Court previously rejected a similar argument made by Plaintiffs in this context. District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *22.

²³ As discussed supra, while Plaintiffs attempt to cure the defects in their 2008 Complaint by adding language that suggests alternative medications were more effective or safer than Risperdal, the specific examples alleged are insufficient to eliminate the conclusory nature of these assertions. (See Compl. ¶¶ 5, 115, 153, 180, 256). For example, in April 1995, the FDA found that Defendants provided inadequate clinical studies to demonstrate whether Risperdal was safe and efficacious to treat patients with dementia. In a letter from the FDA to Defendants, the FDA stated the finding that risperdone reduces agitation in a sample of patients with dementia does not prove that the effect of risperdone is in any way specific to dementia." See Compl. ¶ 174. Such allegation only suggests that Risperdal was not conclusively found effective for off-label purposes; this does not relate to the inferiority of Risperdal to other drugs. In addition, some parts of the Complaint are simply too vague to support any conclusions of Risperdal's inferiority. The Complaint states: "On January 5, 1999, the FDA issued an untitled letter reprimanding Defendants for promoting Risperdal to physicians for the treatment of the elderly. In a letter from the FDA to Todd McIntyre, Janssen's Director of Regulatory Affairs, the agency found that certain promotional materials were false and misleading campaign to promote Risperdal to geriatric patients." Compl. ¶ 177. From Plaintiffs' description, the Court cannot infer that the allegedly "false" and "misleading" information suggests that Risperdal is somehow inferior to other drugs. Similarly, from Plaintiffs' description it is not clear whether the FDA's purported findings in that letter were related to on- or off-label uses of the drug. Even if these findings do relate to off-label uses and suggest that Risperdal is inferior, Plaintiffs do not allege that any of their insureds are elderly patients who are taking Risperdal.

determined that this alleged injury did not satisfy the requisite pleading of concrete financial loss for RICO claims.” District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *22 (citing McLaughlin v. American Tobacco Co., 522 F.3d 215, 228–29 (2d Cir. 2008)). Stated differently, a cognizable RICO injury cannot be solely based upon inducement, since this cannot be considered a “concrete financial loss” without proper allegations that the drug was inferior or otherwise ineffective. Indeed, “[w]ithout alleging that a product failed to perform as advertised, a Plaintiff has received the benefit of his bargain and has no basis to recover purchase costs.” District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *32 (citing Williams v. Purdue Pharm. Co., 297 F. Supp. 2d 171, 176 (D.D.C. 2003)). Therefore, Plaintiffs do not plead a concrete financial loss based on Risperdal being included on their formulary “absent allegations that the drug was inferior on some level and worth less than what they paid for it.” Id. Because Plaintiffs fail to sufficiently allege a cognizable RICO injury under federal or New Jersey law, they lack standing to bring such claims. As will be discussed below, even if Plaintiffs can allege injury, they fail to sufficiently allege the remaining elements of a RICO claim.

2. Causation

Defendants argue that Plaintiffs’ Complaint does not allege a direct relationship between Defendants’ marketing activities and Plaintiff’s injury. Defendants further claim that Plaintiffs’ theory of causation 1) improperly rests on a series of sweeping and conclusory statements, 2) involves multiple steps, innumerable factors, and the independent decisions of unnamed intermediaries, and 3) is too indirect and speculative to satisfy RICO’s proximate cause requirement. Plaintiffs counter that proximate cause is a flexible concept, and they have satisfied this requirement by alleging that the chain of

causation *directly* links Plaintiffs, the parties who pay, to Defendants, the parties who benefitted from the alleged fraud. Specifically, physicians and PBMs received the allegedly misleading and fraudulent information disseminated by Defendants; in turn, the recipients of the fraudulent misrepresentations then performed their necessary, intended and foreseeable act: prescribing the drug.

The Supreme Court has held that “a plaintiff may sue under § 1964(c) only if the alleged RICO violation was the proximate cause of the plaintiff’s injury.” Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 453 (2006) (citing Holmes v. Securities Investor Protection Corp., 503 U.S. 258, 268 (1992)). “When a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led directly to the plaintiff’s injuries.” Anza, 547 U.S. at 461 (2006). In determining proximate cause, courts consider: (1) the directness of the injury; (2) any difficulties in apportioning damages; (3) whether the law can be vindicated by another, more directly injured party. Holmes, 502 U.S. at 269-70. In other words, the proximate cause requirement ensures that 1) there are no independent variables that could account for a plaintiff’s injuries, 2) there is no risk of duplicative recoveries by plaintiffs, and 3) there are no more immediate victims better situated to sue for the injuries alleged. Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639, 658 (2008). Importantly, while first-party reliance is not a required element of a civil RICO claim (independently, or as a part of the proximate cause analysis), “the complete absence of reliance may prevent the plaintiff from establishing proximate cause.” Id. at 658–59.

Plaintiffs argue that by alleging in detail Defendants’ deliberate action to “unlawfully” promote Risperdal for off-label uses and that Plaintiffs were directly

targeted by Defendants' scheme, Plaintiffs have sufficiently alleged causation. For example, Plaintiff alleges that "Defendants embarked on a comprehensive and carefully-orchestrated scheme to promote Risperdal for 'off-label use' . . . through a fraudulent and deceptive marketing program"; Defendants' "promotional scheme corrupted the information process relied upon by physicians in their medical decision-making" and thereby caused physicians to "wr[i]te off-label prescriptions for Risperdal for use by their patients"; and Plaintiffs have suffered injury because "physicians continue to prescribe, and Plaintiffs and the Class continue to pay for, Risperdal to treat off-label uses." (Compl. ¶¶ 2, 107-10, 256, 282, 289). While Plaintiffs have gone to great lengths to chronicle Defendants' alleged conduct, they fail to allege the connection between Defendants' misrepresentation and Plaintiffs' injuries. See Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris Inc., 171 F.3d 912, 935 (3d Cir. 1999) (holding that proximate cause was lacking where "the link between defendants' alleged fraud -- providing false information regarding the safety of their products -- and plaintiffs' injuries [was] too attenuated . . ."). Indeed, Plaintiffs' allegations are too remote to satisfy the causation prong because they noticeably fail to allege that physicians or PBMs relied on any specific misrepresentation made by Defendants. In fact,

"[e]stablishing that Plaintiffs' injuries were caused by Defendants' misconduct would require an inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit. In other words, each physician who prescribed [Risperdal] . . . would have to be questioned as to whether his or her independent medical judgment was influenced by Defendants' misrepresentations, and to what extent.

Ironworkers Local Union No. 68 v. AstraZeneca Pharms., L.P., 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008). Simply put, such an individualized inquiry would require

allegations that off-label prescriptions were written by doctors (and ultimately paid for by Plaintiffs) as a direct result of Defendants' alleged misconduct.

Here, Plaintiffs allege in a conclusory fashion that physicians relied on Defendants' misrepresentations regarding Risperdal. But, Plaintiffs may not aver "causation by way of generalized allegations and aggregate proof," see In re Schering-Plough I, 2009 U.S. Dist. LEXIS 58900, at *89, because there are numerous factors that could influence a physician when deciding to prescribe a certain drug. See UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 135 (2d Cir. 2010) ("An individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing [the drug], and the physician's knowledge regarding the side effects of [the drug] are all considerations that would have been taken into account in addition to the alleged misrepresentations distributed by [the defendant]."); Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 382 (D.N.J. 2004) (quoting Leibowitz v. Ortho Pharmaceutical Corp., 224 Pa. Super. 418, 431, 307 A.2d 449 (Pa. Super. 1973)) ("[It] is for the prescribing physician to use his own independent medical judgment, taking into account the data supplied to him from the drug manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug."'). Absent any reliance, Plaintiffs' injuries of overpayment "could have resulted from factors other than [Defendants'] alleged acts of fraud," such as a physician's independent medical judgment to prescribe Risperdal. Anza, 547 U.S. at 458-59; see Allegheny Gen. Hosp. v. Philip Morris, Inc., 228 F.3d 429, 445 (3d Cir. 2000) (dismissing a RICO claim where asserted harm was "indirect, remote, and many steps away from the alleged cause").

Accordingly, without sufficient allegations of direct reliance, Plaintiffs have not properly alleged that Defendants' misrepresentations were the "but for" cause of their injuries. See Southeast Laborers Health & Welfare Fund v. Bayer Corp., 655 F. Supp. 2d 1270, 1280–81 (S.D. Fla. 2009) ("Calculation of Plaintiff's losses would be purely speculative [It] necessarily would require an analysis of whether or not a particular physician ever received or relied on Bayer's allegedly fraudulent statements, and whether or not a physician, knowing the risk vs. benefit of Trasylol, would still have used it during an operation.").²⁴

Equally unpersuasive is Plaintiffs' argument that they are the intended, foreseeable victim of Defendants' conduct. See Hemi Group, LLC v. City of N.Y., 130 S. Ct. 983, 992 (2010) (proximate cause inquiry is focused "on the directness of the relationship between the conduct and the harm" and does not turn on whether harm to plaintiff was "foreseeable," "intended" or "desired"); Allegheny, 228 F.3d at 439, 441 (no direct injury even in instances where defendants had "specific intent to harm" plaintiffs).

Moreover, Plaintiffs fail to allege sufficiently that the PBMs relied on Defendants' misrepresentations when making formulary recommendations to Plaintiffs. In fact, not only do Plaintiffs have to allege that the PBMs relied on, or were influenced by Defendants' fraudulent marketing, they also have to allege that Plaintiffs solely relied on the PBMs' recommendations to put Risperdal on their formularies in order to satisfy

²⁴ This Court previously opined that Plaintiffs may not "ever properly plead proximate causation, as required by Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 268 (1992)" District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *35.

the proximate cause element of RICO.²⁵ See Bridge, 553 U.S. at 658 (standing for the proposition that the proximate cause analysis under RICO ensures that there are no independent variables that could account for a plaintiff's injuries). Plaintiffs do not allege that their PBMs ever received Defendants' information, or that their PBMs had any communication with Defendants. Importantly, there are no allegations that Plaintiffs, physicians or PBMs were influenced by Defendants' conduct or information. See Id.; see also Southern Illinois Laborers' & Employers Health & Welfare Fund v. Pfizer Inc., No. 08-5175, 2009 U.S. Dist. LEXIS 91414 (S.D.N.Y. Sept. 30, 2009) ("Based on the allegations as currently ple[d] . . . Plaintiffs do not allege that the PBDMs in fact relied on Plaintiffs' misrepresentations regarding the cost effectiveness, efficacy, or safety of Lipitor when the PBDMs decided to include Lipitor on the recommended formularies."). Therefore, this Court holds that Plaintiffs have failed to properly plead proximate cause.

3. Enterprise

As in District 1199P I, Defendants have not briefed the issue or disputed the adequacy of Plaintiff's allegations regarding the "enterprise" element of RICO. This Court has explained:

An 'enterprise' includes 'any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.' 18 U.S.C. § 1961(4). A RICO enterprise is 'an entity [made up of] a group of persons associated together for the common purpose of engaging in a course of conduct.' United States v. Turkette, 452 U.S. 576, 583, 101 S. Ct. 2524, 69 L. Ed. 2d 246 (1981). To establish the existence of an enterprise, a plaintiff must prove that (1) the enterprise is an ongoing organization with some sort of framework or superstructure for making or carrying out decisions; (2) the members of the enterprise function as a continuing unit with established duties; and (3) the enterprise must be separate and apart from the pattern

²⁵ Plaintiffs state in the Complaint that they "rely *almost* exclusively on their PBM to make their formulary decisions." (Compl. ¶ 110).

of activity in which it engages. Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 789-90 (3d Cir. 1984). However, as the rules of pleading require nothing more at this early juncture than a bare allegation, where a plaintiff identifies the ‘entities it believed were the enterprises that had been marshalled [sic] against it,’ a plaintiff sufficiently alleges the existence of an enterprise. Id. at 790.

District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *36-37.

Here, Plaintiffs allege that the enterprise at issue included “Defendants, the network of marketing firms employing physicians and research organizations, contracting with third-party advertisers, proliferation firms and outside consultants, and was used to promote the off-label use of Risperdal to accomplish the common goal of increasing profits by increasing the use and off-label use of Risperdal.” This Court finds that Plaintiffs have sufficiently pled the existence of an enterprise.

4. Racketeering Activity

Defendants argue that Plaintiffs have failed to allege at least two predicate acts of mail fraud, wire fraud, or bribery under the applicable pleading requirements. In response, Plaintiffs argue that they properly allege that Defendants used thousands of mail and interstate wire communications to create and manage their fraudulent scheme to market the off-label uses of Risperdal, which have not been proven safe or effective for these uses. Specifically, Plaintiffs point to Defendants’ 1) fraudulent “Dear Doctor” letters, 2) fraudulent CME presentations, and 3) general publication strategy.²⁶

This Court previously explained that

[t]o allege a RICO violation, a plaintiff must articulate a pattern of racketeering activity, i.e., predicate acts. See Bonavitacola Elec. Contr., Inc. v. Boro Developers, Inc., 87 Fed. Appx. 227, 231 (3d Cir. 2003)

²⁶ The Court notes that Plaintiffs do not address whether they have sufficiently alleged bribery as a predicate act. However, this Court will nonetheless assess the sufficiency of the Complaint regarding such act under RICO.

(citations omitted). The claim ‘must include the allegation of at least two (2) racketeering acts.’ Zellner v. Monroe County Mun. Waste Mgmt. Auth., No. 07-1976, 2008 U.S. Dist. LEXIS 57769, at *20 (M.D. Pa. July 28, 2008). When fraud is the predicate act, a plaintiff must satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9(b). See Warden v. McLelland, 288 F.3d 105, 114 (3d Cir. 2002). Specifically, Rule 9(b) states ‘a party must state with particularity the circumstances constituting fraud or mistake.’ Fed. R. Civ. P. 9(b).

District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *38-39. To satisfy the 9(b) “particularity,” a Plaintiff must “plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure or substantiation into a fraud allegation.” Id. (citing Frederico v. Home Depot, 507 F.3d 188 (3d Cir. 2007)).²⁷

To satisfy the pleading requirements for racketeering activity, Plaintiffs first allege that the predicate acts are mail and wire fraud.²⁸ To plead mail and wire fraud under the heightened 9(b) standard, a Plaintiff must “‘identify the purpose of the mailing within the defendant’s fraudulent scheme and specify the fraudulent statement, the time, place, and speaker and content of the alleged misrepresentation.’” Id. (quoting Annulli v. Panikkar, 200 F.3d 189, 200 n. 10 (3d Cir. 1999)). In other words, Plaintiffs’ “pleading must contain the ‘who, what, when and where details of the alleged fraud.’” Id. (quoting Allen Neurosurgical Assoc., Inc. v. Lehigh Valley Health Network, No. 99-4653, 2001 U.S. Dist. LEXIS 284, at *8 (E.D. Pa. Jan. 18, 2001)). “The purpose of Rule 9(b) is to provide notice of the ‘precise misconduct’ with which defendants are charged” in order to

²⁷ Plaintiff argues that the Court should relax the Rule 9(b) standard because without the benefit of discovery, specific internal corporate mechanisms and operations underlying and in furtherance of Defendants’ fraudulent scheme are within the exclusive knowledge and understanding of Defendants. However, by their own admission, Plaintiffs have had the benefit of some pre-complaint discovery, which allowed Plaintiff access to more than 20 million pages of Defendants’ corporate records.

²⁸ “The Third Circuit permits federal common law or ‘garden variety’ fraud, including mail and wire fraud.” District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *39 (citing Tabas v. Tabas, 47 F.3d 1280, 1290 (3d Cir.), cert denied, 515 U.S. 1118 (1995)). The two elements of a mail and wire fraud charge are 1) a scheme to defraud; and 2) mailing or wiring in furtherance of the scheme to defraud. Id. (citing Greenberg v. Brewster, 816 F. Supp. 1039, 1049 (E.D. Pa. 1993)).

give them an opportunity to respond meaningfully to the complaint, “and to prevent false or unsubstantiated charges.” Rolo v. City of Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998).

Plaintiffs fail to meet the Rule 9(b) pleading standard. As this Court previously held, even “[u]pon a liberal construction of Plaintiff’s Complaint, this Court cannot discern a communication that arguably rises to the level of specificity needed to satisfy 9(b)’s heightened pleading requirement.” Id. (citing Bonavitacola, 87 Fed. Appx. at 231). Indeed, while Plaintiffs claim that the “Complaint goes well beyond what this Court required in District 1199P I to identify the ‘date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into’ their allegation of mail and wire fraud,” Plaintiffs fail to provide the necessary specificity under 9(b). (Opposition Memo p 24).

Plaintiffs first point to Defendants’ “Dear Doctor” letters. See Id. at p 24. In the Complaint, Plaintiffs allege that pursuant to the FDA’s request, Defendants sent letters to health care professionals to add certain language to Risperdal’s warnings. These letters, Plaintiffs allege, continued to misrepresent Risperdal’s risks and “deliberately minimiz[ed] the risk with Risperdal and omit[ed] the warning to monitor certain patients on Risperdal.” (Compl. ¶¶ 162–66). While Plaintiffs provide detailed information with regard to the content of the letters, Plaintiffs fail to allege with particularity how these letters directly impacted Plaintiffs, or how they have been made in furtherance of the alleged “scheme” of off-label promotion of Risperdal. See Briksza v. Moloney, No. 08-01785, 2009 U.S. Dist. LEXIS 52205, at *26–27 (D.N.J. June 19, 2009) (stating that, among other deficiencies, the plaintiff failed to allege a specific instance where the

defendant used the Federal Mail System, and as such, did not meet the pleading requirements for mail fraud under the racketeering prong of RICO); see also In re Schering-Plough I, 2009 U.S. Dist. LEXIS 58900, at *95 (stating that “plaintiffs must identify the predicate acts of racketeering that ‘directly’ injure them”). Rather, Plaintiffs state generally that the letter was sent “to all health care professionals likely to prescribe Risperdal” and that “[b]y sending this woefully inadequate letter, Defendants prevented physicians and patients from adequately understanding the severe risks associated with Risperdal.” (Compl. ¶¶ 165-64). These allegations are inadequate.

Next, Plaintiffs point to Defendants’ allegedly fraudulent CME presentations. Plaintiffs allege that because Defendants knew that FDA regulations prohibited them from pro-actively disseminating information regarding the off-label uses of Risperdal, Defendants encouraged affiliated CME provider physicians to “plant” persons in the audience to make such requests so that false information could be conveyed. Id. at ¶¶ 28-29, 82. To that end, Plaintiffs allege that Defendant planned and coordinated the CMEs by “extensive use of the wires and mails, including the mailing of invitations to physicians, the mailing of proposals to the accrediting institutions, booking of hotels and airplane tickets, the arrangement of meals, the scheduling of telephone conference calls, the development and modification of tactical plans, and the coordination of Risperdal presentation content to be present at the event.” Id. at ¶ 215. However, the Court finds that these generalized allegations do not provide the requisite particularity on how these seminars purportedly affected or influenced Plaintiffs in any manner. In particular, Plaintiffs never once allege that any of Defendants communicated with any of the individual consumers or third-party payor plaintiffs. There are no allegations that any

Plaintiff or representative, or agent, of Plaintiffs received information from Defendants regarding these CMEs. Indeed, the only allegations regarding these CMEs refer to those made by Defendants to other third parties. Hence, there are no particularized allegations of mail or wire fraud involving any of the named Plaintiffs with respect to the fraudulent CMEs.

Finally, Plaintiffs' argument regarding Defendants' publication strategy is similarly unconvincing. The Complaint generally asserts that Defendants "implemented a national uniform marketing, advertising and promotion campaign" in their efforts to promote, advertise, and sell Risperdal for off-label uses. Compl., ¶ 202; see also ¶¶ 203-06. In furtherance of this scheme, Plaintiffs allege that Defendants paid key opinion leaders and influential local physicians to disseminate false and misleading information to physicians prescribing Risperdal. However, Plaintiffs fail to specifically allege how Defendants used the Federal Mail System to further their scheme in this respect. Also, for substantially the same reasons as stated above, Plaintiffs fail to allege how the publication strategy affected or influenced Plaintiffs in any manner. Accordingly, these allegations also fall short of Rule 9(b) pleading requirements. See Compl. ¶¶ 224-262 (making general assertions such as: "[c]onducting marketing and promotion of Risperdal under the guise of continuing medical education;" "Defendants would generate favorable articles touting the off-label use of Risperdal . . .").

Plaintiffs also allege that they satisfy the predicate act requirement because Defendants engaged in bribery. In the Complaint, Plaintiffs allege that Defendants engaged in "[m]ultiple instances of bribery in violation of state statutes" by providing physicians with financial incentives, such as expensive dinners and lavish vacations.

Compl. ¶¶ 244, 323. “While bribery does not invoke the heightened pleading requirements of Rule 9(b), Plaintiffs must satisfy the more liberal pleading requirements of Rule 8(a) to adequately plead bribery as a predicate act.” District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *47. As this Court previously held and applies with equal force here: “Plaintiffs make no effort to delineate the elements of bribery nor do they cite to any statute which does so, and thus, Plaintiffs have failed to put Defendants on notice as to what laws they are alleged to have violated.” Id. (citing Lockheed Martin Corp. v. Boeing Co., 357 F. Supp. 2d 1350, 1374–75 (M.D. Fla. 2005)). Indeed, the Complaint does not assert any instances where Defendants provided remuneration to a physician and thereby caused the physician to prescribe Risperdal when it was not in the patient’s best interests. Nor do Plaintiffs allege that any “bribes” to physicians resulted in prescriptions for which Plaintiffs should not have paid. Instead, Plaintiffs simply allege that Defendants committed “[m]ultiple instances of bribery in violation of state statutes.” (Compl., ¶ 323).

In sum, because Plaintiffs have not sufficiently alleged any of the elements, except for enterprise, as required under RICO and NJRICO, they have not sufficiently plead their RICO claims under federal or New Jersey law, and the Court grants Defendants’ motion to dismiss Counts I and III of the Complaint.

B. Count II: Conspiracy to Commit RICO

Defendants assert that Plaintiffs RICO conspiracy claim fails because it is premised on Plaintiffs’ deficient federal RICO claim. Relying on this Court’s prior decision, Defendants state that a conspiracy claim under 18 U.S.C. § 1962(d) must be dismissed where the underlying substantive RICO cause of action is legally insufficient.

See District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *60. Plaintiffs do not counter the accuracy of this Court's conclusion of the law, but simply state that because they have satisfied the elements of the RICO claim, it follows that they also satisfy the RICO conspiracy claim.

As previously held, "Plaintiffs' allegations that Defendants violated § 1962(d) by conspiring to violate § 1962(c) in this case fail as a matter of law because Plaintiffs have not sufficiently plead a federal RICO claim under § 1962(c)." Indeed, "[a]ny claim under section 1962(d) based on conspiracy to violate the other subsections of section 1962 necessarily must fail if the substantive claims are themselves deficient."²⁹ Magnum v. Archdiocese of Phila., 253 Fed. Appx. 224, 229 (3d Cir. Pa. 2007) (quoting Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153, 1191 (3d Cir. 1993)). Because Plaintiffs fail to properly allege a RICO claim, Plaintiffs conspiracy to commit RICO also fails. Accordingly, the Court also grants Defendants' motion to dismiss Count II, the RICO conspiracy claim, of Plaintiffs Complaint.

C. Counts IV and V: New Jersey Consumer Fraud Act ("NJCF") and New Jersey Unfair and Deceptive Acts and Practices

Defendants argue that Plaintiffs' claim under the NJCFA fails because Plaintiffs do not plead causation with the particularity required by Rule 9(b). In addition, Defendants claim that Plaintiffs lack standing to sue under the NJCFA, since TPP's are not considered "consumers" within the meaning of the statute to bring suit. Plaintiffs counter that they have adequately pled the causation requirement because it is more relaxed than the stringent RICO standard. In addition, Plaintiffs contend that while the

²⁹ Even more specifically, this Court holds that Plaintiffs fail to cite a cognizable injury, which forecloses any claim brought under § 1962(d). See Magnum, 253 Fed. Appx. at 229 (citing 18 U.S.C. § 1964(c)) (stating that "a plaintiff alleging a civil RICO violation under *either* § 1962(c) or (d) must plead a cognizable injury to 'business or property' under § 1964(c)").

law regarding standing is not settled, there is ample authority to support their standing in this case as “consumers.”

To properly allege a NJCFA claim, a plaintiff has to adequately aver the following elements: “‘(1) unlawful conduct by the defendants; (2) an ascertainable loss on the part of the plaintiff; and (3) a causal relationship between the defendants’ unlawful conduct and the plaintiff’s ascertainable loss.’” Indian Brand Farms, Inc. v. Novartis Crop Prot., Inc., 617 F.3d 207, 218 (3d Cir. 2010) (quoting N.J. Citizen Action v. Schering-Plough Corp., 367 N.J. Super. 8 (App. Div. 2003)). “Under the first element, a plaintiff must [allege] that the ‘defendant engaged in deception, fraud, false pretense, false promise, or misrepresentation,’ but need not establish either intent or detrimental reliance on the misrepresentation.” Marcus v. BMW of N. Am., LLC, No. 08-5859, 2010 U.S. Dist. LEXIS 122908 (D.N.J. Nov. 19, 2010) (citing Gennari v. Weichert Co. Realtors, 148 N.J. 582, 605-08, 691 A.2d 350 (1997)). To allege an ascertainable loss, Plaintiffs must aver that they “suffer[ed] . . . ‘either an out-of-pocket loss or a demonstration of loss in value’ that is ‘quantifiable or measurable.’” Id. (citing Thiedemann v. Mercedes-Benz U.S.A., LLC, 183 N.J. 234, 248 (2005)). In fact, the ascertainable loss requirement is met when a consumer receives less than what was promised. Zebersky v. Bed Bath & Beyond, Inc., No. 06-cv-1735, 2006 U.S. Dist. LEXIS 86451 (D.N.J. Nov. 28, 2006), at *5 (citing Union Ink Co. v. AT&T Corp., 352 N.J. Super. 617, 646 (App. Div. 2002)). Indeed, “in order to recover damages under NJCFA, a plaintiff must ‘[allege] that the unlawful consumer fraud caused [its] loss.’” Cannon v. Cherry Hill Toyota, Inc., 161 F. Supp. 2d 362, 374 (D.N.J. 2001) (citing Cox v. Sears Roebuck & Co., 138 N.J. 2, 23 (1994)).

Moreover, the pleading requirements of Rule 9(b), which require information such as the date, time, place of the alleged fraud, or some other “measure of substantiation” into the fraud allegation, apply to a NJCFA claim. Slim CD, Inc. v. Heartland Payment Sys., No. 06-2256, 2007 U.S. Dist. LEXIS 62536 (D.N.J. Aug. 22, 2007), at *28, 32 (citing F.D.I.C. v. Bathgate, 27 F.3d 850, 876 (3d Cir. 1994) and Lum, 361 F.3d at 223–24).

Plaintiffs’ consumer fraud claim fails to meet the threshold Rule 9(b) pleading requirement for causation. As discussed supra, Plaintiffs’ theory of causation in this action is too speculative and attenuated to be cognizable. Indeed, Plaintiffs do not allege sufficiently how Defendants’ allegedly fraudulent promotion of Risperdal for off-label uses caused Plaintiffs to suffer injury. As such, this failure is fatal to Plaintiffs’ NJCFA claim. Allegheny, 228 F.3d at 445-46 (dismissing state law fraud and negligent misrepresentation claims for lack of proximate causation when RICO claims failed for same reasons); Steamfitters, 171 F.3d at 934 (“[t]he same principles that lead us to conclude that plaintiffs’ antitrust and RICO claims were properly dismissed lead to the inevitable conclusion that their state-law claims must also fail.”); Schering-Plough I, 2009 U.S. Dist. LEXIS 58900, at *111 (dismissing NJCFA, negligent misrepresentation, and fraud claims for failure to plead causation in RICO claims). In addition, Plaintiffs fail to allege the “causal relationship” requirement under the statute. Plaintiffs do not plead that they, or any of their prescribing doctors, received a misrepresentation of fact from Defendants and relied on that misrepresentation in deciding to prescribe Risperdal

or in deciding to place Risperdal on their formulary -- which are Plaintiffs' asserted injuries. Without adequate allegations of causation, Plaintiffs' NJCFA claim fails.³⁰

Regarding Plaintiffs' claim under New Jersey's Unfair and Deceptive Acts and Practices, this Court notes that Plaintiffs cite to N.J.S.A. § 56:8-1, et seq., as the statutory basis. However, § 56:8-1 is New Jersey's Consumer Fraud Act. Indeed, there is no New Jersey statute entitled "Unfair and Deceptive Acts and Practices."³¹ As such, because there is no statutory basis to assert this claim, Count V is dismissed.

D. Count VI: Violations of State Consumer Protection and Unfair and Deceptive Acts or Practices Statutes

In Count VI, Plaintiffs allege that Defendants violated 49 other states' consumer protection and unfair and deceptive acts or practices statutes (not including New Jersey). This Court finds, however, that every state's consumer fraud statutes may not have the same elements as the NJCFA. Indeed, as this Court previously held, "there is no basis for this Court to conclude that all the elements of consumer fraud statutes in other states mirror the statute in New Jersey." Kalow & Springnut, LLP v. Commence Corp., No. 07-3447, 2009 U.S. Dist. LEXIS 320, at *13 (D.N.J. Jan. 5, 2009). "[T]his sort of 'catch-all' listing of statutes does not meet the most basic pleading requirements." In re Toshiba Am. HD DVD Mktg. & Sales Practices Litig., No. 08-939, 2009 U.S. Dist. LEXIS 82833, at *41 (D.N.J. Sept. 10, 2009) (citation omitted). Accordingly, Count VI of Plaintiffs' Complaint is dismissed.

³⁰ This Court acknowledges that some courts have held that TPPs are not consumers entitled to sue under the NJCFA. See In re Schering-Plough I, 2009 U.S. Dist. LEXIS 58900, at *116 (citing J & R Ice Cream Corp. v. Cal. Smoothie Licensing Corp., 31 F.3d 1259, 1273 (3d Cir. 1994)). This Court need not decide whether TPPs are consumers within the scope of the statute, because Plaintiffs' allegations are insufficient to support their NJCFA claim.

³¹ See Green v. Am. Online (AOL), 318 F.3d 465, 473 (3d Cir. 2003) (standing for the proposition that the NJCFA is N.J.S.A. §§ 56:8-1, et seq.).

E. Count VII and Count X: Negligent Misrepresentation and Fraud

Defendants argue that Plaintiffs' negligent misrepresentation and fraud claims should be dismissed because of Plaintiffs' failure to adequately allege causation and the required reliance element.

"Under New Jersey law, a claim for negligent misrepresentation requires a plaintiff to establish that defendant made an incorrect statement, upon which he or she justifiably relied, causing economic loss." Henderson v. Volvo Cars of N. Am. LLC, No. 09-4146, 2010 U.S. Dist. LEXIS 73624, at *34 (D.N.J. July 21, 2010) (citing McClellan v. Feit, 376 N.J. Super. 305, 317 (App. Div. 2005)). For fraud, "a plaintiff must allege (1) a material misrepresentation of fact; (2) knowledge or belief by the defendant of its falsity; (3) intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damage." In re Schering-Plough I, 2009 U.S. Dist. LEXIS 58900, at *116 (citing Gennari, 148 N.J. at 610). The pleading requirements of Rule 9(b) apply to these claims. Id.

As this Court stated supra, Plaintiffs have not alleged that physicians relied on Defendants' misrepresentations about Risperdal. Without these allegations that Plaintiffs, physicians, or PBMs relied on Defendants' information, Plaintiffs cannot properly allege the reliance element of both negligent misrepresentation and fraud. Indeed,

Plaintiffs fraud and negligent misrepresentation claims do not meet the stringent requirements for pleading fraud under Rule 9(b). Plaintiffs do not state with the requisite particularity the circumstances of the alleged fraud or otherwise inject precision into their allegations. As has the Court already discussed, Plaintiffs make sweeping allegations concerning Defendants' alleged off-label promotion of the Subject Drugs. Yet, Plaintiffs do not plead a single instance in which they, themselves, [their PBMs], or any of their prescribing doctors received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe one of the Subject Drugs to Plaintiffs.

Id. at *117.

In addition, “proximate cause is an essential element of both fraudulent misrepresentation and negligent misrepresentation claims.” Bouriez v. Carnegie Mellon Univ., 585 F.3d 765, 771 (3d Cir. 2009) (citing Allegheny, 228 F.3d at 445). Since this Court held, supra, that Plaintiffs failed to meet the proximate cause requirement under RICO and NJRICO, Plaintiffs fail to meet the proximate cause requirement under both negligent misrepresentation and fraud. Therefore, Counts VII and X are dismissed.

F. Count VIII: Unjust Enrichment

Defendants argue that New Jersey law only recognizes unjust enrichment as a quasi-contractual doctrine, and accordingly, a claim of unjust enrichment fails where, as here, it sounds exclusively in tort. Plaintiffs assert that their unjust enrichment claim does not sound in tort, but rather, in quantum meruit based on an implied contract. For an unjust enrichment claim, “New Jersey law requires a plaintiff to ‘show both that defendant received a benefit and that retention of that benefit without payment would be unjust.’” In re Ford Motor Co. E-350 Van Prods. Liab. Litig., 2011 U.S. Dist. LEXIS 16504, at *29–30 (D.N.J. Feb. 16, 2011) (citing Iliadis v. Wal-Mart Stores, Inc., 191 N.J. 88, 110 (2007) (quotation omitted)).

Plaintiffs claim that Defendants received monies, a benefit, from Plaintiffs -- overpayments and Defendants’ increased profits -- which were excessive and unreasonable for the purchase of Risperdal. Regardless of whether Plaintiffs’ claim in this context sounds in tort, this Court holds that this alleged overpayment is insufficient under an unjust enrichment claim where Plaintiffs have not alleged that any “beneficiaries, insured, or employees taking Risperdal ‘received [an] inadequate [or]

inferior [drug] or even worse, suffered personal injuries as a result of Defendants' alleged misrepresentations." District 1199P I, 2008 U.S. Dist. LEXIS 103526, at *30 (citing Maio, 221 F.3d at 488). Without such allegations, Plaintiffs have not adequately pled a benefit that is unjust; rather, as pled, Plaintiffs received the benefit of their bargain.³² Therefore, Plaintiffs' claim of unjust enrichment is dismissed.

G. Plaintiffs' Count IX: Civil Conspiracy

Under New Jersey law, a claim for civil conspiracy cannot survive without a viable underlying tort, and because all of Plaintiffs' tort claims fail as a matter of law, Plaintiffs' civil conspiracy claim must be dismissed. See Allegheny, 228 F.3d at 446 (citation omitted) (stating that a civil conspiracy claim requires an underlying cause of action); see also King's Choice Neckwear, Inc. v. FedEx Corp., No. 07-CV-0275, 2007 U.S. Dist. LEXIS 93843, at *10 (D.N.J. Dec. 20, 2007) (citation omitted) (stating that "[a] civil conspiracy claim requires an underlying cause of action apart from the conspiracy itself"). Since this Court has dismissed Counts I-VIII and X, and there is no underlying tort claim, Plaintiffs' civil conspiracy claim fails.

DATED: March 21, 2011

/s/ Freda L. Wolfson
Freda L. Wolfson U.S.D.J.

³² In re Schering-Plough I also cites Steamfitters, 171 F.3d at 936-37 for the proposition that "where tort claims cannot be maintained, [the] rationale for permitting equitable action for restitution also disappears, given lack of underlying wrong on which to premise equitable claim." 2008 U.S. Dist. LEXIS 103526, at *43-44.